



APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/109,864	07/06/98	NI	J PF354P1
			EXAMINER

022195 HM12/0907  
HUMAN GENOME SCIENCES INC  
9410 KEY WEST AVENUE  
ROCKVILLE MD 20850

ART UNIT	PAPER NUMBER
1646	4

DATE MAILED:

09/07/99

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on \_\_\_\_\_
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- ☒ Claim(s) 1 to 28 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☒ Claim(s) 1 to 28 are subject to restriction or election requirement.

#### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

—SEE OFFICE ACTION ON THE FOLLOWING PAGES—

Art Unit: 1646

Claims 1 to 28 are pending in the instant application.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 to 15, drawn to an isolated polynucleotide, a vector and host cell containing that polynucleotide and a method of using the host cell to produce a protein, classified in class 435, subclass 69.1.
- II. Claims 16 and 17, drawn to an isolated polypeptide, classified in class 530, subclass 350.
- III. Claims 18 and 19, drawn to an antibody, classified in class 530, subclass 388.22.
- IV. Claims 20, 21, 23, 24 and 27, drawn to a method of treatment by administering a protein, classified in class 514, subclass 2.
- V. Claim 22, drawn to a diagnostic method employing nucleic acid hybridization, classified in class 435, subclass 6.
- VI. Claims 25, 26 and 28, drawn to gene therapy, classified in class 935, subclass 62.

The inventions are distinct, each from the other because:

The nucleic acid that is invention I, the protein that is invention II and the antibody that is invention III are three structurally and functionally different chemical compounds each of which can be made and used without any one or more of the other compounds. Lack of unity is shown because these compounds lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

Art Unit: 1646

Invention I is related to inventions V and VI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid product as claimed could be in a process of producing a protein, as claimed, which is a process that is materially different from the diagnostic process that is invention V or the gene therapy method that is invention VI.

Inventions II and IV are also related as product and process of use. The isolated protein that is invention II can be used in an assay to detect ligands thereto, which is a method that is materially different from the method of treatment that is invention IV.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter restriction for examination purposes as indicated is proper.

A telephone call was made to Kenley Hoover on 12 August of 1999 to request an oral election to the above restriction requirement, at which time Applicant requested that the requirement be submitted in writing.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Art Unit: 1646


Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee can be reached at (703) 308-2731.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
JOHN ULM  
PRIMARY EXAMINER  
GROUP 1800